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March 17, 2010

Via ECF and Federal Express

Honorable Mark Falk, U.S.M.J.
United States District Court
Frank R. Lautenberg U.S.P.O. & Courthouse
Room 457
1 Federal Square
Newark, NJ 07101

Re: ***Eli Lilly and Co. v. Actavis et al.***
Civil Case No. 07-3770 (DMC)(MF)

Dear Judge Falk:

We write on behalf of all seven Defendants in this litigation in response and opposition to Plaintiff Eli Lilly and Company's most recent request to push back the May 18, 2010 trial date set by Judge Cavanaugh.

On February 26, 2010, Lilly asked that the parties jointly request that the May 18, 2010 trial date be pushed back. Defendants responded that they wished to proceed as the Court had ordered. On March 3, Lilly again asked Defendants to submit a request to move the May 18 trial date. After Defendants reiterated their desire to maintain the May 18 date, Lilly filed a request with this Court on March 4. Lilly's only stated basis for seeking to push back the trial date was its decision to change lead counsel for the second time in this case, and to do so nearly three years into the litigation.

On March 8, 2010, this Court held a conference with the parties to consider Lilly's request. The Court informed the parties that the May 18, 2010 trial date would remain in place, absent agreement of the parties. At no time during that conference did Lilly mention anything about a May trial in another litigation, though the Court gave Lilly ample opportunity to do so, and even though Lilly must have known about it at the time. Approximately three hours after the conference with the Court, Lilly sent Defendants a letter asserting – for the first time – that it has another trial starting on May 3, 2010, this one in Canada. On this basis, Lilly once again asked Defendants to agree to push back the May 18 trial date. Defendants again responded that they wished to proceed on May 18 as ordered (twice).

Honorable Mark Falk, U.S.M.J.

March 17, 2010

Page 2

On March 12, citing its newly-discovered Canadian trial, Lilly wrote this Court asking that Lilly be permitted to present its case-in-chief during the week of May 18. Alternatively, armed with a new reason for seeking to delay the trial in this Hatch-Waxman case, Lilly again asked this Court move the May 18 trial date. Lilly's requests should be denied.

Lilly's "belief" that its witnesses "may be called" to testify in this purported Canadian litigation the week of May 24 is not a legitimate reason to permit Lilly to present its case first at trial. As Lilly well knows, the trial will involve invalidity and unenforceability – defenses on which Defendants bear the burden of proof and thus present their case first and last.¹ As Lilly also well knows, permitting Lilly to "respond" to Defendants' proofs before Defendants present them not only would be illogical and confusing, but severely prejudicial to Defendants. For these reasons alone, Lilly could not reasonably expect this Court to grant such relief. Indeed, the relief Lilly really seeks is to delay the trial, but Lilly's "belief" that its witnesses "may be called" to testify in the Canadian litigation the week of May 24 provides no more legitimate basis for delaying the trial than it does for permitting Lilly to prejudice Defendants by switching the order at trial. Lilly's second request to push back the May 18 trial date should be denied for this reason alone, but there is more.

Since the Court set the trial date back on February 24, Defendants and their witnesses have been making preparations for a May 18 trial. Defense counsel have relied on this date when scheduling other litigation commitments, and witnesses have arranged schedules around this date. Pushing back the trial at this point could be extremely problematic now that other commitments have been accepted, both by Defendants and their witnesses. Defendants' March 5 correspondence to this Court sets forth just some of the commitments that defense counsel have between June and September 2010.

Further, Defendants submit that the May 18 date should not be moved given that Lilly has provided no explanation whatsoever for its failure to raise this issue sooner. While Lilly apologizes to the Court for failing to raise it prior to the March 8 teleconference, the fact is that the parties had been discussing pretrial and trial scheduling *nearly two months* prior to March 8. At no time during the parties' back and forth did Lilly ever raise this purported Canadian trial, and at no time since March 8 has Lilly explained its failure to raise this issue earlier.

Nearly a year ago, on May 1, 2009, Lilly submitted a letter to this Court repeatedly requesting a trial date in "Q1 or early Q2 of 2010." (Ex. 1). Lilly received precisely what it asked for with the May 18 trial date. This, again, is a Hatch-Waxman ANDA case – a Hatch-Waxman case that has been pending for nearly three years. Defendants thus request that this case proceed to trial on May 18, 2010, and that Defendants be permitted to present their

¹ The party with the burden of proof (here Defendants) is entitled to present evidence first and last at trial. See *Anheuser-Bush, Inc. v. John Labatt Ltd.*, 89 F.3d 1339, 1344 (8th Cir. 1996); *Martin v. Chesebrough-Pond's, Inc.*, 614 F.2d 498, 501 (5th Cir. 1980); *Troncoso v. Martin Archery, Inc.*, 127 F.R.D. 190, 191 (E.D. Wash. 1989).

Honorable Mark Falk, U.S.M.J.

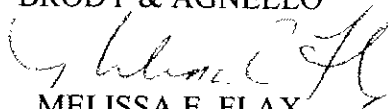
March 17, 2010

Page 3

case-in-chief at the start of trial. Lilly has offered this Court no legitimate reason to alter the current schedule or order of proof at trial.

Respectfully submitted,

CARELLA, BYRNE, CECCHI, OLSTEIN
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MELISSA E. FLAX

MEF

Attachment

cc: Counsel of Record (w/attachment) (via ECF)

EXHIBIT 1



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May 1, 2009

By Facsimile

The Honorable Mark Falk
Magistrate Judge
U.S. District Court for the District of New Jersey
U.S.P.O. & Courthouse, Room 457
1 Federal Square
Newark, NJ 07102

**Re: *Eli Lilly & Co. v. Actavis Elizabeth LLC, et al.*,
Civ. A. No. 07-3770 (D.N.J.) (DMC) (MF)**

Dear Judge Falk:

We represent Plaintiff Eli Lilly and Company in this action, together with Pepper Hamilton, LLP. This letter concerns: (i) the Court's previous suggestion that the parties propose a *Markman* schedule for resolution of any claim construction issues, and (ii) Plaintiff's new request that, in light of the 30-month FDA stay which expires November 26, 2010, the Court now tentatively set a trial schedule in Q1 or early Q2 of 2010, so that the parties can plan accordingly to avoid the potential last-minute disruption of a launch at risk, or a preliminary injunction motion to prevent such a launch.

Markman Claim Construction Issues

At the March 13, 2009 Hearing, Your Honor suggested that the parties propose a *Markman* claim construction schedule (Hr'g Tr. 42-43, Mar. 13, 2009) (Exhibit A). Defendants urged then that if there was a need for any claim construction, that could be handled in the context of the dispositive motion briefing, set for filing on May 13, or shortly before trial (Hr'g Tr. 43-44). Plaintiff Lilly continues to believe that a claim construction ruling may be necessary at least to resolve certain potential invalidity defenses currently raised by Defendant Sun.

In particular, the '590 patent-in-suit claims are method of use claims which require the use of atomoxetine to treat a patient for ADHD. Lilly contends the claims exclude the use of atomoxetine to treat patients for any disorder other than ADHD, such as depression.



The Honorable Mark Falk
May 1, 2009
Page 2

Lilly is considering filing one or more Summary Judgment motions on May 13 that may require such claim construction rulings. Lilly is agreeable to having those claim construction issues resolved as part of the summary judgment briefing schedule, and has recently confirmed this approach with counsel for Apotex.

Tentative Trial Schedule

Lilly also wishes to alert the Court, as indicated at the March 13 Hearing, that the 30-month statutory stay of ANDA approval in this case expires on November 26, 2010. Lilly does not know if any of the Defendants would launch "at risk." However, so that the Court and the parties may plan appropriately, and to avoid burdening the Court with emergency proceedings, including motions for a preliminary injunction, Plaintiff respectfully requests that the Court set a tentative trial date in Q1 or early Q2 of 2010, or provide an indication as to when trial would occur, in order to assure that a decision is obtained prior to November 26, 2010. Absent such a tentative trial date or other indication from the Court, the parties will face increasing uncertainty as to when a final decision might be rendered, leading to potential risk of an at-risk launch or other disruptive event, including last-minute preliminary injunction or other motions to prevent such a launch.

Our local counsel has indicated that it may be difficult to obtain a trial date on the Court's docket in 2009. Consequently, we request the Court's guidance in scheduling a tentative trial date in early 2010, so that a decision can be finalized prior to November 26, 2010.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Thomas H. Beck".

Thomas H. Beck

Enclosures

cc. The Honorable Dennis M. Cavanaugh, U.S.D.J. (via overnight mail)
Counsel of Record (via email)